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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/735,477 | 12/11/2003 | David C. Hovda | S-16 | 2479 |

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| EXAMINER | |
|---|---|
| TOY, ALEX B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3739 | |

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/735,477 | HOVDA, DAVID C. | |
| | Examiner | Art Unit | |
| | Alex B. Toy | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *9 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Information Disclosure Statement*

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the at least one optic fiber attached to the treatment device as specified in claim 6 must be shown. How the tools specified in claim 9 fit through the access device 4 must be shown. How a conductive medium is provided from a source external to the disc as specified in claim 12 must be shown. How a dye is injected into the disc as specified in claim 24 must be shown. Otherwise, the feature(s) must be canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 9, 12, 17, 21, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 6, the disclosure does not specify how to make and/or use the invention, wherein at least one of the optic fibers is attached to the treatment device.

Regarding claim 9, the disclosure does not enable the use of the large tools claimed with the access device 4 as shown or described.

Regarding claim 12, the disclosure does not show or describe any inlet or outlet ports to allow a conductive medium to be provided from a source external to the disc.

Regarding claim 17, the disclosure does not specify how to measure a void created by the ablating of tissue.

Regarding claim 21, the disclosure does not specify how to measure shrinkage of tissue resulting from the coagulating of tissue.

Regarding claim 24, the disclosure does not specify how a dye is injected into the disc.

### *Claim Objections*

Claims 9 and 14 are objected to because of the following informalities: Claims 9 and 14 recite the limitation "the treatment device." There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination it is assumed that applicant intended Claims 9 and 14 to depend from claim 4 instead of claim 2. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 10-18, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Underwood et al. (U.S. Pat. No. 6,277,112 B1).

Regarding claim 1, Underwood et al. disclose a method for treating an intervertebral disc comprising:

Advancing at least one optic fiber 324 into a nucleus of the disc via the access device 302 (col. 26, ln. 53-59, col. 27, ln. 2-3 and 6-8, and Figs. 16 and 17); and

Viewing an interior of the disc using at least one of the optic fibers (Figs. 17 and 18).

Regarding claim 2, Underwood et al. disclose the method of claim 1, further comprising advancing an access device into the disc to create a passageway into the disc with the access device (col. 27, ln. 44-49).

Regarding claim 4, Underwood et al. disclose the method of claims 1 and 2, further comprising:

Advancing a treatment device 310 through the access device 302 (Fig. 16); and

Activating the treatment device to treat the disc (col. 27, ln. 64 – col. 28, ln. 16 and Fig. 18).

Regarding claim 5, Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device occurs prior to viewing the interior of the disc (Fig. 18). Since the treatment device of Underwood et al. must first remove tissue from

the interior of the disc in order for the optical fiber to be able to view the interior, the treatment device is inherently activated prior to viewing the interior of the disc.

Regarding claim 6, Underwood et al. disclose the method of claims 1, 2, and 4, wherein at least one of the optic fibers 324 is attached to the treatment device 310 (Fig. 17).

Regarding claim 10, Underwood et al. disclose the method of claims 1, 2, and 4, wherein the treatment device includes at least one active electrode 357 and a return electrode 350, wherein activating the treatment device comprises applying a high frequency voltage between the active and return electrodes (col. 27, ln. 64-67 and Fig. 17).

Regarding claim 11, Underwood et al. disclose the method of claims 1-2, 4, and 10, further comprising using a conductive medium to form a current path between the active and return electrodes (col. 27, ln. 40-42 and 53-58 and Fig. 17)

Regarding claim 12, Underwood et al. disclose the method of claims 1-2, 4, and 10-11, where the conductive medium is provided from a source external to the disc (col. 27, ln. 40-42 and 53-58 and Fig. 17).

Regarding claim 13, Underwood et al. disclose the method of claims 1-2, 4, and 10-11, where the conductive medium is the naturally occurring fluid within the disc. The naturally occurring fluid is inherently present in the disc. Therefore, the conductive medium must inherently comprise at least the naturally occurring fluid.

Regarding claim 14, Underwood et al. disclose the method of claims 1, 2, (and 4) wherein advancing the treatment device comprises advancing the treatment device into a nucleus pulposus of the disc (col. 27, ln. 44-49).

Regarding claim 15, Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device comprises ablating tissue within the disc (col. 27, ln. 64-67 and Figs. 17 and 18).

Regarding claim 16, Underwood et al. disclose the method of claims 1-2, 4, and 15, further comprising observing the effect of the ablating of tissue using the optic fiber (col. 28, ln. 17-18).

Regarding claim 17, Underwood et al. disclose the method of claims 1-2, 4, and 15-16, wherein observing the effect comprises measuring a void created by the ablating of tissue (col. 28, ln. 22-23).

Regarding claim 18, Underwood et al. disclose the method of claims 1-2, 4, and 15-16, wherein observing the effect comprises observing an outer portion of the disc. The device of Underwood et al. is inherently capable of observing an outer portion of the disc when observing the effect of ablation (Fig. 18).

Regarding claim 25, Underwood et al. disclose the method of claim 1, where advancing the at least one optic fiber into the nucleus of the disc via the access device is performed during an open surgical procedure (col. 3, ln. 27-33).

Regarding claim 26, Underwood et al. disclose the method of claim 1, where advancing the at least one optic fiber into the nucleus of the disc via the access device is performed during a percutaneous surgical procedure (col. 4, ln. 46-50).

Claims 1-2, 4, 9, 19-20, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by another embodiment of Underwood et al.

Regarding claim 1, in another embodiment Underwood et al. disclose a method for treating an intervertebral disc comprising:

Advancing at least one optic fiber 280 into a nucleus of the disc via the access device 278 (col. 24, ln. 12-17 and Fig. 13); and

Viewing an interior of the disc using at least one of the optic fibers (Figs. 13-15).

Regarding claim 2, in another embodiment Underwood et al. disclose the method of claim 1, further comprising advancing an access device into the disc to create a passageway into the disc with the access device (col. 24, ln. 30-35).

Regarding claim 4, in another embodiment Underwood et al. disclose the method of claims 1 and 2, further comprising:

Advancing a treatment device 284 through the access device 278 (Figs. 13-15); and

Activating the treatment device to treat the disc (col. 25, ln. 35-38).

Regarding claim 9, in another embodiment Underwood et al. disclose the method of claims 1, 2, (and 4) where the treatment device is selected from a group comprising pituitary rongeurs, curettes, graspers, cutters, drills, and microdebriders (col. 25, ln. 20-34 and Figs. 14 and 15).

Regarding claim 19, in another embodiment Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device comprises coagulating tissue within the disc (col. 3, ln. 48-53). It is noted that causing tissue to shrink constitutes coagulating tissue as evidenced by claim 21.

Regarding claim 20, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19, further comprising observing the effect of the coagulating of tissue using the optic fiber (Fig. 14).

Regarding claim 22, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19-20, wherein observing the effect comprises observing an outer portion of the disc. The device of Underwood et al. is inherently capable of observing an outer portion of the disc when observing the effect (Fig. 15).

Regarding claim 23, in another embodiment Underwood et al. disclose the method of claims 1, 2, and 4, further comprising performing non-invasive imaging prior to or during activating the treatment device (col. 24, ln. 1-15).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 7-8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Underwood et al.

Regarding claim 3, Underwood et al. disclose the method of claims 1 and 2. The claim differs from Underwood et al. in calling for advancing the access device into the disc to comprise separating layers of a fibrous outer portion of the disc to create a passageway into the disc with the access device. Underwood et al., however, disclose another embodiment of their invention in which the access device 702 comprises a needle (as called for by the applicant on page 17, ¶ 70 of the specification) that advances into the disc to separate layers of a fibrous outer portion of the disc to create a passageway into the disc that causes less damage and is re-sealable. (col. 33, ln. 25-34, col. 33, ln. 45-55, and Figs. 34-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of advancing the access device of Underwood et al. comprise separating layers of a fibrous outer portion of the disc to create a passageway into the disc with the access

device in view of another embodiment of Underwood et al. to create a passageway that causes less damage and is re-sealable.

Regarding claim 7, Underwood et al. disclose the method of claims 1, 2, and 4. The claim differs from Underwood et al. in calling for advancing of the at least one optic fiber and viewing the interior of the disc to be performed intermittently through said method. In view of the method disclosed by Underwood et al., however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have intermittently advanced at least one optic fiber and viewed the interior of the disc because the user would obviously remove tissue and intermittently advance at least one optic fiber and view the interior of the disc to see how much tissue had been removed.

Regarding claim 8, Underwood et al. disclose the method of claims 1 and 2. The claim differs from Underwood et al. in calling for advancing the access device to comprise inserting a needle into at least a fibrous outer portion of the disc. Underwood et al., however, disclose another embodiment of their invention in which the access device 702 comprises a needle (as called for by the applicant on page 17, ¶ 70 of the specification) that is inserted into a fibrous outer portion of the disc to create a passageway into the disc that causes less damage and is re-sealable. (col. 33, ln. 25-34, col. 33, ln. 45-55, and Figs. 34-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of advancing the access device of Underwood et al. comprise inserting a needle into at least a fibrous outer portion of the disc in view of another embodiment of Underwood et al. to create a passageway that causes less damage and is re-sealable.

Regarding claim 21, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19-20. The claim differs from another embodiment of Underwood et al. in calling for observing the effect to comprise measuring shrinkage of tissue resulting from the coagulation of tissue. In one embodiment Underwood et al., however, teach measuring a void created by the ablating of tissue (col. 28, ln. 22-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of observing of Underwood et al. comprise measuring shrinkage of tissue resulting from the coagulation of tissue in view of one embodiment of Underwood et al. because it is obvious to use the same method to measure a void to monitor treatment progress, whether the void is created by coagulation or ablation.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Underwood et al. in view of Mulier et al. (U.S. Pat. No. 5,897,553).

Regarding claim 24, Underwood et al. disclose the method of claim 1. The claim differs from Underwood et al. in calling for the method to further comprise injecting a dye into the disc. Mulier et al., however, teach a method for an electrosurgical device with a conductive fluid, wherein a dye is injected with the conductive fluid in order to make the fluid more visible during the procedure (col. 5, ln. 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of Underwood et al. comprise injecting a dye into the disc in view of the teaching of Mulier et al. in order to make the fluid more visible during the procedure.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 5,762,629 to Kambin

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL PEFFLEY
PRIMARY EXAMINER

AT AT
9/23/05